UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SEKISUI AMERICA CORPORATION and SEKISUI MEDICAL CO., LTD., Plaintiffs, v. RICHARD HART and MARIE LOUISE TRUDEL-HART, Defendants.	Civil Action No. 12-CV-3479 (SAS)

REPLY IN SUPPORT OF PLAINTIFFS' MOTION *IN LIMINE* TO EXCLUDE PORTIONS OF THE EXPERT REPORT AND TESTIMONY OF THOMAS D. BECZE

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Plaintiffs Sekisui America Corporation and Sekisui Medical Co., Ltd. (together, "Plaintiffs") respectfully submit this reply in support of Plaintiffs' Motion *in Limine* to Exclude Portions of the Expert Report and Testimony of Thomas D. Becze.

PRELIMINARY STATEMENT

Plaintiffs' motion seeks to exclude Mr. Becze's three-paragraph rebuttal of Plaintiffs' expert, Timothy Ulatowski, on the grounds that Mr. Becze's opinion lacks any reliable basis and is unsupported by any evidentiary analysis. Defendants attempt to obscure the inadequacies of Mr. Becze's rebuttal by defending Mr. Becze's qualifications and stating that Mr. Becze based his opinion on his experience—without providing any explanation of how he did so. But Plaintiffs are not asserting that Mr. Becze is unqualified to offer *any* opinion on any issue related to a 510(k) submission. Plaintiffs are arguing that Mr Becze's cursory opinion regarding the 510(k) submission in this case—an opinion consisting of nothing more than statements that Mr. Ulatowski's detailed analysis was "pure speculation" and "pure conjecture" and that it is "impossible to predict the outcome of a 510(k) submission"—is inadmissible under Rule 702. Mr. Becze seeks to offer this testimony despite numerous shortcomings precluding its admissibility, including that he: (1) did not review the Femtelle 510(k) submission at issue (or even the related correspondence he now claims to have reviewed); (2) failed to demonstrate how his experience allows him to opine on the inner workings of the FDA 510(k) review process such that he can unequivocally declare it "impossible" to predict the outcome of *any* 510(k) submission (especially one he has never read); and (3) undermined his own conclusion by conceding that, in fact, it *is* possible in certain circumstances to predict the outcome of a 510(k) submission.

As the Court recognized at the parties' September 27, 2013 pre-motion conference: "Becze conceded at deposition that he cannot opine on the FemTel 510(k) submissions because

he's not read them and that he agrees that there are circumstances when a submission is likely to fail. He's never worked at the FDA or overseen the 510(k) submission process and cites no reliable basis for his opinion so it seems to me that his opinion on the 510(k) process and FemTel's submissions are beyond his expertise, not to mention he didn't review the submissions." (Nov. 1, 2013 Declaration of Craig Whitney in Support of Plaintiffs Motion *in Limine* to Exclude Portions of the Expert Report and Testimony of Thomas D. Becze ("Nov. 1 Whitney Decl."), Ex. A (Sept. 27, 2013 Tr.) at 24:16-22.) As set forth below and in Plaintiffs' opening brief, Mr. Becze's rebuttal of Mr. Ulatowski's report is inadmissible under Rule 702 and should be excluded.

ARGUMENT

I. MR. BECZE'S CONCLUSION IS NOT GROUNDED IN THE FACTS OR HIS EXPERIENCE.

The portion of Mr. Becze's report rebutting Mr. Ulatowski's opinions is devoid of any supporting facts or data and is not the product of reliable principles and methods. Mr. Becze's proffered testimony summarily dismisses Mr. Ulatowski's conclusions as "pure conjecture" and "impossible" without a proper basis for doing so, requiring its exclusion.

A. Mr. Becze Provides Insufficient Support For His Conclusion.

As Defendants' opposition brief ("Defs.' Opp'n Br.") confirms, the entire rationale for Mr. Becze's conclusion that it is "impossible to predict the outcome of a 510(k) submission" is Mr. Becze's view that a Refusal to File notice is the *only* way to determine whether a 510(k) submission is destined to fail. (Defs.' Opp'n Br. at 4-5.)

In support of this conclusion, Mr. Becze cites to nothing—no data, no studies, no documents from the record, no industry standards. (*See* Nov. 1 Whitney Decl., Ex. C (Becze Report) at 6-7.) Mr. Becze's reasoning is not based on evidentiary analysis, but rather on an *ipse*

dixit, "take my word for it" theory. He does not even review the actual 510(k) submission itself to determine whether his sweeping conclusion is supportable. Indeed, Mr. Becze testified:

> If anyone tells me that something is destined to fail and it's a 510(k) and it's submitted with all of its normal parts and doesn't get a refusal to file, I don't have to read the 510(k) to know that that's not correct.

(Nov. 1 Whitney Decl., Ex. E (Becze Dep.) at 247:24-248:5.)

But Mr. Becze himself concedes that there are circumstances where a 510(k) submission is so deficient that it has no possibility of success. (*Id.* at 257:13-258:18.) Moreover, it is unreliable for Mr. Becze to testify that Mr. Ulatowski's conclusions are "pure conjecture" when Mr. Becze did not base his rebuttal testimony on any of the materials that Mr. Ulatowski used to reach his conclusions. In contrast to Mr. Becze, Mr. Ulatowski analyzed all of the facts underlying the 2007 and 2009 510(k) submissions, read and relied on the actual 510(k) submissions and analyzed the relevant rules and regulations and related correspondence. (Nov. 15, 2013 Declaration of Siobhan Briley in Support of Defendants' Opposition to Plaintiffs' Motion *in Limine* to Exclude Portions of the Report and Testimony of Thomas D. Becze ("Nov. 15 Briley Decl."), Ex. 2 (Ulatowski Report) at 8, 20 n.22, 22 n.35, 24.) Mr. Ulatowski's report lays out the FDA requests for additional information regarding "clinical deficiencies," "data gaps" and "lack of three lab results from inter-lab tests" that were impossible for ADI to provide. (*Id.* at 28-29) As a result of ADI's inability to provide this information, Mr. Ulatowski concluded that the 2009 Femtelle 510(k) submission had no chance of success and Plaintiffs were obligated ultimately to withdraw the Femtelle 510(k) submission. (*Id.* at 32-33.)

In an attempt to justify Mr. Becze's failure to review the 510(k) submission at issue or any other materials related to that submission, Defendants incorrectly contend that Mr. Ulatowski's opinion is based "entirely" on his review of correspondence, and that Mr. Becze reviewed that correspondence. (Defs.' Opp'n Br. at 2.) Mr. Ulatowski's report states what he

considered: "I relied on my 36 plus years of training, knowledge and utilization of the FDA medical device regulations, policies, review procedures and practices in forming my opinions expressed in this document. The list of materials that I considered in forming my opinions is attached as Appendix B." (Nov. 15 Briley Decl., Ex. 2 (Ulatowski Report) at 8.) Included among those materials are the 2007 and 2009 Femtelle 510(k) submissions. (*Id.* at 20 n.22, 22 n.35, 24).) Mr. Ulatowski's analysis of these materials allowed him to reach the same conclusion as the FDA—that the 2009 Femtelle 510(k) submission was insufficient and destined to fail. Defendants' argument that Mr. Ulatowski's analysis consisted only of a review of correspondence is therefore plainly incorrect. Moreover, as discussed below, Mr. Becze did not even review that correspondence in forming his opinion.

Defendants also attempt to justify Mr. Becze's failure to review the Femtelle 510(k) submission by misstating the purpose of Mr. Ulatowski's report and misleadingly arguing that Mr. Ulatowski did not perform a scientific analysis of that submission. This is a red herring. Mr. Ulatowski's expert opinion that the 2009 Femtelle 510(k) submission was destined to fail was not based on the scientific merits of the submission, but rather on the insufficiency of the data and documentation in ADI's possession when such information was necessary for ADI to obtain 510(k) clearance. Therefore, the fact that Mr. Ulatowski did not perform a scientific analysis of the submission is irrelevant.

Defendants further attempt to salvage Mr. Becze's baseless opinion by attaching an untimely declaration from Mr. Becze to their opposition brief, wherein Mr. Becze states: "To assist the Court in reviewing my qualifications, I provide the following additional information," and then goes on to provide additional testimony regarding the 510(k) submission process and Mr. Becze's professional experience. (Nov. 15, 2013 Declaration of Thomas D. Becze in

Support of Defendants' Opposition to Plaintiffs' Motion *in Limine* to Exclude Portions of the Expert Report and Testimony of Thomas D. Becze, ¶ 5.) Having had a full and fair opportunity to opine on Mr. Ulatowski's opinion, and declining to amend his rebuttal report following the parties' pre-motion conference, Mr. Becze should not be permitted to supplement his opinions now with information that he chose not to disclose earlier. Federal Rule of Civil Procedure 26(a)(2) requires expert witnesses to provide a written report containing "a complete statement of all opinions the witness will express and the basis and reasons for them." Opinions or bases for opinions not contained in an expert report should be stricken. *See*, *e.g.*, *Takeda Chem. Indus., Ltd. v. Mylan Labs., Inc.*, No. 04-CV-1966, 2006 U.S. Dist. LEXIS 278, at *4-6 (S.D.N.Y. Jan. 9, 2006) (granting motion to strike expert's opinions from a supplemental affidavit where "those opinions . . . were not contained in [the original] report" despite the argument that the supplemental affidavit "is a simple recitation of facts").

Regardless, even if the Court were to consider Mr. Becze's declaration, Defendants new argument that Mr. Becze based his opinions on the "same correspondence" that Mr. Ulatowski analyzed is wrong. As is clear from his report and testimony, Mr. Becze's opinion is not based on any correspondence with the FDA, and is instead based solely on his unsupported rationale that a Refusal to File is the only basis on which one could predict the outcome of a 510(k) submission.[1] (*See* Nov. 1 Whitney Decl., Ex. E (Becze Dep.) at 247:10-12; *id.* Ex. C (Becze

[1] As noted in Plaintiffs' opening brief, a Refusal to File (actually, Refusal to Accept) is a procedure used by the FDA to ensure that a 510(k) submission is reviewable in the first place, and does not bear on the submission's substance. (*See* Nov. 1 Whitney Decl., Ex. D (Center for Devices & Radiological Health's Premarket Notification 510(k) Refuse to Accept Policy) at 5 ("The reviewer should keep in mind that the purpose of this acceptance review is to ensure reviewability, not the substantial equivalence of the 510(k).").) The Checklist for Acceptance Decision in the Refuse to Accept policy includes "yes" and "no" categories to confirm that certain requirements are included in each submission, such as whether the product is a "device" (Question I.A); the device name (Question I.F.1); photographs of the device (Question I.F.10);

Report) at 6.) Indeed, Mr. Becze's report does not cite to the correspondence from the FDA requesting additional information regarding the 2007 or 2009 Femtelle 510(k) submissions. Mr. Becze cites instead only to two emails between the FDA and Plaintiffs in his rebuttal of Mr. Ulatowski's report—and these two emails are unrelated to his conclusion that Mr. Ulatowski's report is "pure conjecture." (*See* Nov. 15 Briley Decl., Ex. 1 (Becze Report) at 6-7 and App. 2.) These two emails are the *only* FDA correspondence regarding the Femtelle 510(k) submissions that Mr. Becze included in his materials considered. (*See id.*) At his deposition, Mr. Becze vaguely claimed to have reviewed "some" correspondence between the FDA and ADI, but provided no details regarding the correspondence or the requests for additional information the FDA had sent to ADI, or how he accounted for this evidence. (Nov. 1 Whitney Decl., Ex. E (Becze Dep.) at 248:6-12.)

In truth, Mr. Becze's opinion is based on nothing more than his own say so, and is entirely disconnected with any facts relevant to the 510(k) submission at issue in this case. In deciding that it is "impossible" for Mr. Ulatowski to conclude that the 2009 Femtelle 510(k) submission was destined to fail, Mr. Becze did not consider the materials submitted with the 2009 Femtelle 510(k) submission or the issues that emerged in the FDA's numerous requests for more information from ADI. Such failure to consider the material evidence in this case—upon which Mr. Ulatowski relied—renders Mr. Becze's rebuttal testimony unreliable and, therefore, inadmissible.

B. Mr. Becze Does Not Connect His Opinion to His Experience.

In addition to the lack of evidentiary support, Mr. Becze's opinion regarding the 2009 Femtelle 510(k) submission is further unreliable because it is disconnected from any of

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and basic contact information such as the name and address of the submitter (Question II.A). (*See id.* (Premarket Notification (510(k) Checklist for Acceptances Decision).)

Mr. Becze's experience. Defendants claim that Mr. Becze links his opinions to his experience, but fail to provide any explanation of how Mr. Becze's previous experience filing 510(k) submissions informed his decision that it is impossible to know that the Femtelle 510(k) submission at issue in this case was destined to fail. (Defs.' Opp'n Br. at 6-7.) Likewise, Mr. Becze's untimely declaration describes his experience filing 510(k) submissions, but again fails to link that experience to the opinion rendered in this case.

Plaintiffs are not arguing that Mr. Becze could never offer an opinion related to any 510(k) submission. Rather, Plaintiffs are seeking to exclude Mr. Becze's testimony in part because he fails to show how any experience he has regarding other 510(k) submissions allows him to conclude that it was "impossible" for Mr. Ulatowski to opine that the FDA would not approve this specific 510(k) submission at issue, particularly when Mr. Becze did not even review that submission. Unlike Mr. Ulatowski, who spent 36 years at the FDA, Mr. Becze never worked at the FDA or any other government agency. (*See* Nov. 1 Whitney Decl., Ex. E (Becze Dep.) at 22:4-9.) Mr. Becze therefore does not explain how whatever experience he has allowed him to opine that it is impossible to conclude that the 2009 Femtelle 510(k) submission was destined to fail merely because it did not receive a Refusal to File/Accept.

Defendants cite to *Emig v. Electrolux Home Products Inc.*, No. 06-CV-4791 (KMK), 2008 U.S. Dist. LEXIS 68811 (Sept. 11, 2008 S.D.N.Y.), in support of their argument that Mr. Becze's opinion should be admitted based on his experience. That case is inapposite, however, because not only did the expert in that case link experience in the area to his opinion, he also "analyze[d] the instructions at issue," and compared them to similar instructions used in the industry. *Id.* at *31. Here, Mr. Becze failed to link his experience to his opinion and did not read the Femtelle 510(k) submission—the very document on which he opines. Likewise, in

McCullock v. H.B. Fuller Co., 61 F.3d 1038 (2d Cir. 1995), the expert at issue tied his general experience to his opinion and based his opinion on "a range of factors," including expertise, studies and multiple data sources. *Id.* at 1044. In contrast, Mr. Becze's opinion rebutting Mr. Ulatowski's opinion is not based on "a range of factors," as he fails to cite to any supporting data, studies or analysis, and again the opinion is not linked to his experience.

Defendants do *not*—and cannot—assert that Mr. Becze based his opinion on the substance of the 510(k) submissions in this case, or the specific requests from the FDA to ADI for additional information. Unlike Mr. Becze's rebuttal, Mr. Ulatowski's report tied the information in ADI's possession—including any reports and data regarding the Femtelle submission—to what the FDA required for approval, and determined that there was no chance that ADI's 2009 Femtelle 510(k) submission would be approved by the FDA. Mr. Becze's rebuttal fails to rely on any supporting facts or data or demonstrate how his expertise allows him to reach his unsupported conclusion. Therefore, Mr. Becze's three-paragraph rebuttal of Mr. Ulatowski's expert report fails to meet the minimum standards of Rule 702 and should be excluded.

CONCLUSION

For the reasons set forth above and in Plaintiffs' opening brief, Plaintiffs respectfully request that the Court grant Plaintiffs' motion *in limine* to exclude Mr. Becze's proffered rebuttal testimony to Mr. Ulatowski's expert report.

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